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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,521	09/26/2001	Makoto Ito	1422-0493P	9464
2292	7590	03/23/2004	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH			NASHED, NASHAAT T	
PO BOX 747			ART UNIT	PAPER NUMBER
FALLS CHURCH, VA 22040-0747			1652	

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/937,521	Applicant(s) ITO, MAKOTO	
	Examiner Nashaat T. Nashed, Ph. D.	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 15-20 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8 is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-14, and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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The application has been amended as requested in the communication filed January 29, 2004.

As indicated in the previous Office action, claims directed to methods of using an allowable product would be rejoined, when the product claim is found allowable.

Claims 1-14 and 21 are under consideration.

The disclosure is objected to because of the following informalities: The specification contains several undefined abbreviation or acronyms, see for example GM1a. GM1a is an abbreviated name to a specific chemical name. The IUPAC article filed with response clearly indicates that GM1a is an acceptable abbreviation, and not a proper chemical name. The specification does not identify the proper chemical name or the chemical structure of the compound being cited.

Appropriate correction is required.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The claims remain generally narrative and indefinite, failing to conform to current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors. The amendment of the claims has not overcome all the shortcomings. The claims should be rewritten in idiomatic American English and removing any redundancy that may exist in a claim. For example, claim 1 part (D) is directed to nucleic acid sequence different from that of, presumably, part A-C via degeneracy of the genetic code. Applicant should note part (A) of claim 1 is directed to all nucleic acid sequences encoding the amino acid sequence of SEQ ID NO: 14, which claim all the variants in part D that differ from part (A) and (B) because of the multiplicity of codons for amino acids. Another example, claim 6 directed to a "transformant" which includes man. Applicants are advised to rephrase all claims in proper English, in particular, claims 2, 3, 6, 10, and 14.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 9-14, and 21 are rejected under 35 U.S.C., 112, first paragraph, for the reasons set forth in the prior Office action, mailed October 29, 2003.

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Applicants argue that disclosure amended claim 1 to include hybridization conditions, and argue that the claims, as amended, fully comply with 35 U. S. C. 112, first paragraph.

Applicants' arguments filed 1/29/04 have been fully considered, but they are not deemed to be persuasive. Enablement requires a disclosure sufficient to allow a person of skill in the art to practice the full scope of the claimed invention without undue experimentation. The previous Office action sets out a *prima facie* case of non-enablement, explaining by sound scientific reasoning why a person of ordinary skill in the art would doubt that the guidance of the specification would enable practice of the full scope of the claimed invention without undue experimentation. Applicants have presented no evidence or, indeed, any arguments to establish the adequacy of the disclosure to enable the scope of the instant claims. Applicants merely assert that the claims are enabled. Applicants make no effort to explain why they consider the disclosure of one mammalian ceramidase with specific to be enabling with respect to every other ceramidase activity encoded by any nucleic acid sequence which hybridizes under the incomplete and low stringent hybridization conditions in claim 1, part (C). Conclusory statements unsupported by evidence or scientific reasoning are insufficient to overcome the *prima facie* case of non-enablement set out in the previous Office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following are the reasons for the rejections:

- (a) Claim 3 contain abbreviations or acronyms such as GM1a and sulfatide, which render the claims indefinite because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. The specification does not define the abbreviation and one of ordinary skill in the art does not know what they are.
- (b) The phrase "at a temperature of ((T_m of the oligonucleotide) -25 degree C)" in claim 14 renders the claim indefinite because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. For examination purposes only the phrase is assumed to mean "at 25 degree C below the melting temperature of a duplex formed from the nucleic acid of claim 1 and a primer has strand length of 15 to 40 [nucleotide]."
- (c) Also, claim 14 is indefinite and unsearchable because it is dependent on claim 1, which contains the hybridization language in part (C). The nucleic

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acid that hybridizes to the nucleic acid of part (A) or (B) under the hybridization conditions of (C) may contain unknown segments that can't be searched.

- (d) The clause "derived from a region having a sequence characteristic of a ceramidase" in new claim 21 renders the claim indefinite because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. One of ordinary skill in the art would not know which sequence is characteristic to ceramidase, and the specification does not teach any characteristic sequences for ceramidases. For examination purposes, it is assumed that the applicants intend to say "corresponds to nucleic acid sequence encoding amino acid residues in a ceramidase".

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 14 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marra et al. (Database: EST, Accession number AA920146) in view of the state of the art.

The EST teach a nucleic acid sequence consisting of 451 nucleotide in which residues 1-157 are identical to residues 1893-1049 of SEQ ID NO: 15 of the instant application. Since the intended use of an EST or fragment thereof is a probe or a primer to identify a full length coding sequence, it would have been obvious to one of ordinary skill in the art at the time of invention to synthesize a fragment of 15-40 oligonucleotide corresponding to 5'-end of the EST and use as a probe to probe a gene or cDNA library to identify and isolate a nucleic acid containing an open reading frame. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time was made and was as a whole, clearly *prima facie* obvious.

Claim 8 is allowed.

Claims limited to the ceramidase of SEQ ID NO: 14 or encoded by nucleic acid sequence which hybridizes to SEQ ID NO: 15 under the high stringent conditions and wash conditions on page 43 and nucleic acid encoding the same would be considered favorably.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Nashaat T. Nashed, Ph. D.** whose telephone number is 571-272-0934. The examiner can normally be reached on **MTTF**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Ponnathapura Achutamurthy** can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nashaat T. Nashed, Ph. D.
Primary Examiner
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